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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/506,740

09/03/2004

Marcus Geese

220401-1020

3579

7590

10/06/2006

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EXAMINER

HIRIYANNA, KELAGINAMANE T

ART UNIT

PAPER NUMBER

1633

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/506,740

Applicant(s)

GEESE ET AL.

Examiner

Kelaginamane T. Hirianna

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

The inventions as claimed are classified into following groups:

- I. Claim 1, 2-7, 10-15 and 27 drawn to a pharmaceutical composition comprising a nucleic acid molecule coding for short chain dehydrogenase or a variant or a fragment or a nucleic acid effector, to a use of a nucleic acid molecule of the short chain dehydrogenase or a variant or a fragment and to a kit comprising nucleic acids
- II. Claim 1, 8-9, 11-15 and 27 drawn to a pharmaceutical composition comprising a polypeptide of the short chain dehydrogenase or a variant or a fragment, to a use of a polypeptide of the short chain dehydrogenase or a variant or a fragment and to a kit comprising polypeptide or fusion polypeptide.
- III. Claim 1, 11-15 and 27 drawn to a pharmaceutical composition comprising a effector of SCAD polypeptide of the short chain dehydrogenase or a variant or a fragment or an effector of said polypeptide, to a use of a an effector of said polypeptide and to a kit comprising antibody or another receptor.
- IV. Claims 16-19 and 26 drawn to a transgenic animal exhibiting a modified expression of SCAD homologous polypeptide, to a recombinant host cell exhibiting a modified expression of said polypeptide and the use of a nucleic acid molecule for the preparation of a non-human animal.

- V. Claims 20-22 and 23-25 drawn to a method of identifying a polypeptide involved in the regulation of energy homeostasis and or triglyceride metabolism in a mammal using SCAD polypeptide binding assay and to a method of screening for an agent which modulates the interaction of a SCAD homologous polypeptide to a target agent and to a method of screening for an agent that modulates the activity of said polypeptide.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

The inventions listed as Groups I and V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: a) a prior art of record exists regarding a feature linking technical claims 1-27 i.e., SCAD gene and the polypeptide and their use and b) further Group I invention is specifically designed for compositions and use of compositions for gene therapy with SCAD nucleic acids, vectors, effectors of gene expression and a kit comprising the same where as the invention of group II specifically designed for compositions and use of compositions of protein or polypeptide therapy with SCAD proteins and a kit comprising the same, Group III is drawn effectors of said polypeptides and SCAD sequences, antibodies and a kit comprising said components. Nucleic acids and their derivatives are structurally and operationally distinct from proteins and polypeptides and both are structurally distinct from the effectors that include antibodies. Group IV invention involves live transgenic non-human animals that come under statutorily distinct classification from Group I, II, III and V inventions. Group V inventions are distinct and different from inventions I-IV as it involves a method of screening for compounds or agents that interfere or interact with SCAD protein interactions and/ or metabolism of triglycerides. The mode of operation, and the effects evaluated in each of the above invention is thus distinct and different from the other. The invention as whole thus lacks unity under PCT

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rule. Therefore, a search and examination for the patentability of the above inventive groups together would generate an undue search burden on the examiner. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species: Should group I be elected from above, the.

- (a). Applicant is required chose a single nucleic acid molecule among the recited in claim 3.
- (b). Applicant is required chose a single nucleic acid molecule among the recited in claim 10.
- (c). Applicant is required chose a single disease or disorder among the recited in claim 13.
- (d). Applicant is required chose a single nucleic acid molecule among the recited in claim 10.
- (e). Applicant is required chose a single nucleic acid molecule among the recited in claim 14.
- (f). Applicant is required chose a single nucleic acid molecule among the recited in claim 15.
- (g). Applicant is required chose one among nucleic components (a)-(c) and (9) for the kit among the kit components recited in claim 27.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

This application contains claims directed to the following patentably distinct species: Should group II be elected from above, the.

- (a). Applicant is required chose a single disease or disorder among the recited in claim 13.
- (b). Applicant is required chose one among polypeptide components (d)-(e) for the kit among the components recited in claim 27.

The species are independent or distinct because they are clinically distinct.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

This application contains claims directed to the following patentably distinct species: Should group III be elected from above, the.

(a). Applicant is required chose a single disease or disorder among the recited in claim 13.

(b). Applicant is required chose component (f) for the kit among the components recited in claim 27.

The species are independent or distinct because they are clinically distinct.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

This application contains claims directed to the following patentably distinct species: Should group V be elected from above, the

(a). Applicant is required chose a single disease or disorder among the recited in claim 24 and 25.

The species are independent or distinct because they are clinically distinct.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Kelaginamane Hiriyanna* whose telephone number is (571) 272-3307. The examiner can normally be reached Monday through Friday from 9 AM-5PM. Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst *William N. Phillips*, whose telephone number is (571) 272-0548. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Dave Nguyen*, may be


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reached at (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). When calling please have your application serial number or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. For all other customer support, please call the USPTO call center (UCC) at (800) 786-9199.

Kelaginamane T. Hiriyanne

Patent Examiner

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SUMESH KAUSHAL, PH.D.
PRIMARY EXAMINER